

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA,)	
ex rel. CHINYELU DUXBURY)	
Relator,)	
v.)	Case No. 03-cv-12189-RWZ
ORTH BIOTECH PRODUCTS, L.P.,)	Judge Rya W. Zobel
Defendant.)	Magistrate Judge Dein
)	

**RELATOR DUXBURY’S OPPOSITION
TO
ORTHO’S 12-31-09 “BRIEF”**

I. INTRODUCTION

Ortho presents not a motion¹ but a “Brief” that neither requests relief nor cites to a single case for its central untenable contention: an “original source” with “direct and independent knowledge” of the “*essential facts*” of a “*scheme*” must also have “direct knowledge” of all the geographic and temporal activities regarding the “*scheme*” and every “*false claim*” resulting from it. Instead of doing things the right way, Ortho does it the wrong way in order to urge this Court to issue an order preventing Relator from pursuing, on remand, all the “*false claims*” for Medicare reimbursement alleged to have resulted from Ortho’s nation-wide multi-year “Kickback scheme”.

¹ Instead of filing a “*Motion*”, Ortho filed a “*Brief*” “On The Proper Scope Of Relator’s Remaining Kickback Claims”. The Court at the 12-10-09 Status Conference set a schedule in anticipation of Ortho filing a “*motion*”. The Docket entry states:

Motions due by 12/31/2009; opposition 1/15/10; 5 page reply 1/22/10; *Motion Hearing* set for 2/4/2010 02:30 PM in Courtroom 12 before Judge Rya W. Zobel.). (Urso, Lisa) (Entered: 12/10/2009).

12-10-09 Docket Entry (emphasis added).

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Although Relator has been qualified by this Court, affirmed on appeal, as the “original source” of her “*claim*” alleging Ortho engaged in a nationwide fraudulent “Kickback *scheme*” regarding its drug Procrit between 1992 to at least 2006, nevertheless, Ortho makes the startling assertion that, “this Court and the First Circuit *already have ruled* that relator is *barred* from recovering anything after July 1998”, the date Relator’s employment with Ortho terminated. Ortho’s Brief at 1. There being no such ruling, Ortho points instead to this Court’s ruling that Relator did not have “direct knowledge of [Ortho’s] activities ... after he was terminated in 1998 and therefore he qualifies as an original source only with regard to *allegations* concerning the 1992-1998 time period”. *Id.* at 3 (emphasis added). Ortho’s “Brief” is based on the false premise that this ruling regarding Relator’s lack of “direct knowledge” of Ortho’s “*scheme*” activities after his employment ended means Relator “*lost* his status as an ‘original source’” for the post-employment period of the “*scheme*”. Ortho’s Brief at 1.

Ortho’s contention that Relator’s lack of “direct knowledge” of Ortho’s activities after Relator’s July 1998 termination means Relator, “ceased being an “original source” of the post-1998 “*scheme*” and therefore Relator was “barred from recovering anything after July 1998” (“Brief” at 1, 6) ignores one salient material truth: this Court, in response to Ortho’s motion, has already ruled that Relator had obtained “direct and independent knowledge” of all the “*essential facts*” of the “*scheme*” during the 1992-1998 period of his employment thus qualifying Relator as the “original source” of the *entire* “Kickback scheme”. See **Section IIA**.

Throughout the “Brief” Ortho conflates Relator’s “Kickback *claim*” and the “*false claims*” Relator is entitled to recover under it as “relator’s remaining *Kickback claims*”.

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“Brief” at 1-9. This allows Ortho to obscure the fact that there is just one nationwide “Kickback scheme” of long duration to which Relator had to qualify as the “original source” – a “*scheme*” that resulted in the submission of many “*false claims*” for Medicare reimbursement. In this way Ortho concludes its “Brief” by *suggesting* to the Court that it must “strictly limit” its “original source” jurisdiction over the “Kickback claim” geographically and temporally to just the eight “Duxbury accounts” during the period of Relator’s employment within the statute of limitations i.e. November 6, 1997 to mid-July 1998, the date Duxbury’s employment terminated.²

Ortho’s attempt to muddle the distinction between Relator’s “Kickback claim” and the “*false claims*” Relator is attempting to recover cannot hide the fundamental legal realities that: 1) this Court ruled that Relator satisfied the “original source” jurisdictional requirements that pertain to the “Kickback *claim*”; and, 2) the 1st Circuit ruled that Relator satisfied the Rule 9(b) pleading requirements that applied to the eight representative “*false claims*” of Ortho’s nationwide scheme. See **Section IIB**.

Despite Ortho’s prodigious attempt to obfuscate the issue, it remains that the statute, case-law, and the rulings of this Court and the 1st Circuit hold to the following:

² The “Brief” concludes with this statement”:

[T]his Court *should enter* an order strictly limiting relator’s claims on remand to the kickback allegations contained in paragraph 211 of the Amended Complaint that are based on [Ortho’s] conduct purportedly occurring between November 6, 1997 and the date of Duxbury’s termination in mid-July 1998.

As the 1st Circuit noted in its decision remanding this case, Paragraph 211 of Relator’s “1st Amended Complaint” entitled “Relator Duxbury’s Accounts” “sets forth allegations of kickbacks provided by [Ortho] that resulted in the submission of false claims by eight healthcare providers in the Western United States”. *US ex rel Duxbury v. Ortho Biotech Products, LP*, 579 F.3d 13, 30 (1st Cir. 2009).

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Relator's "direct and independent knowledge" of the "*essential facts*" of Ortho's nationwide multi-year "Kickback scheme" obtained during the period of Relator's employment qualified Relator to be the "original source" of the *entire* scheme, including that part of the scheme that continued after Relator's employment ended. Once Relator qualified as an "original source" of this complex "*scheme*" of long duration and satisfied the Rule 9(b) requirement of pleading "representative examples" of the "*scheme*", the statute and the Rules did not impose on Relator any additional requirement. Relator does not have to demonstrate "direct knowledge" of all of the activities of the "*scheme*" or all the "*false claims*" resulting from the "*scheme*" in order to pursue discovery. Once Relator qualified as an "original source" of this complex scheme of long duration, Relator was empowered to pursue the geographic and temporal reach of the "*scheme*" in order to recover all of the "*false claims*" within the statute of limitations that were wrongfully induced by it.³ See **Section III**.

II. RELATOR HAS SATISFIED THE "ORIGINAL SOURCE" AND RULE 9(b) REQUIREMENTS**IIA. The Court Has Ruled Relator Obtained 'Direct And Independent Knowledge' Of The 'Essential Facts' Of The 'Kickback Scheme' During His Employment.**

It cannot be questioned that Relator obtained "direct and independent knowledge" of all the "*essential facts*" of the "Kickback scheme" during his 1992-1998 employment. This issue was settled when the Court resolved Ortho's motion to dismiss.

³ Relator does not contest that the six-year statute of limitations, 31 USC §3731(b), limits Relator's recovery going back to November 1997.

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The premise of Ortho's motion to dismiss that the "Public Disclosure Bar", 31 USC 3730(e)(4)(A), applied to Relator's "Kickback claim" was its assertion that the "*essential facts* supporting" the "claim" had been "publicly disclosed" in the AWP MDL litigation.⁴ Ortho also argued that McClellan's "Kickback claim" was barred under the "First to File Bar", USC 3730(b)(5), because it was "based on *essentially the same facts* that Relator Duxbury already asserted".⁵

This Court agreed with Ortho on both points. The Court ruled the "Public Disclosure Bar" was triggered because Duxbury's "Kickback allegations ... are the same as those alleged in the MCC".⁶ The Court ruled further that since McClellan "does not assert any new claims ... but only adds additional supporting facts to the legal claims previously made" by Duxbury he had to also qualify as an "original source" of the "Kickback" claim.⁷ However, the Court agreed with Ortho that "even if he qualified ...[he] would be barred by the "First To File Bar" which "precludes a subsequent relator's claim that alleges the defendant engaged in the *same type of wrongdoing* as that claimed in a prior action even if the allegations cover a different time period or location within a company".⁸

⁴ 1-17-07 Ortho's Memorandum in support of its motion to dismiss at 8.

⁵ Id. at 20 (emphasis added).

⁶ *US ex rel. Duxbury v. Ortho Biotech Products LP*, 551 F. Supp 2d 100, 108 (USDC DMa 2007).

⁷ Id. at 109.

⁸ Id. at 110-111.

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In its decision ruling in Ortho's favor on these points, the Court analyzed in detail the allegations in Relator's Amended complaint regarding the "Kickback claim" and the public disclosure of the AWP MDL allegations in the Master Consolidated Class Action Complaint (MCC). The Court noted that in the 10-6-06 1st Amended Complaint the following was alleged by the Relator about the "Kickback scheme":

Relators allege that beginning in 1992, [Ortho] undertook a scheme to give kickbacks to providers and hospitals to induce them to prescribe Procrit. The kickbacks allegedly included free samples, off-invoice discounts, rebates, consulting fees, educational grants, payments to participate in studies or trials and advisory board honoraria. Relators allege that the kickbacks caused providers and hospitals to submit false claims for payment to Medicare. They claim the time period of the false claims is from December 1992 to the present.

US ex rel. Duxbury v. Ortho Biotech Products LP, 551 F. Supp 2d 100, 104 (USDC DMa 2007).

The Court compared the Complaint allegations to the following AWP MDL allegations in the MCC:

The MCC alleged that [Ortho] ... engaged in widespread fraudulent conduct, including kickbacks, improper use of free samples, discounts, rebates and other hidden and improper inducements and price reductions.

US ex rel. Duxbury v. Ortho Biotech Products LP, 551 F. Supp 2d 100, 106 (USDC DMa 2007).

The Court concluded the allegations in the Complaint and MCC regarding the "Kickback scheme" "are the *same*".⁹ Because the Court found that the "Kickback claim" allegations were the "*same*" in both the Complaint and MCC, the Court had to determine whether Duxbury had "direct and independent knowledge" of the information underlying the "Kickback claim" in order to determine if Relator qualified under the "Original

⁹ Id. at 108.

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Source" exception, USC 3730(e)(B) to the "Public Disclosure Bar. The Court found that Relator's employment as a Product and Account Specialist provided Relator with "knowledge of the alleged fraud" that was "both *independent* and *direct*". The Court found as follows:

In his position as a Product Specialist and later Regional Key Account Specialist for [Ortho's] Western Division Oncology sales force, Duxbury was responsible for the promotion and sale of Procrit in the western United States. The complaint alleges that, at [Ortho's] direction, he gave providers free samples of Procrit and instructed the providers to submit Medicare claims for the samples, ... and directly provided discounts, rebates, educational grants, and other off-invoice discounts to providers to lower the actual acquisition cost of Procrit. ... *His knowledge of the alleged fraud is both independent and direct.*

US ex rel. Duxbury v. Ortho Biotech Products LP, 551 F. Supp 2d 100, 109 (USDC DMA 2007).

The Court having ruled, at Ortho's urging, that the "*essential facts*" of the "Kickback claim" and the MCC allegations were the "same" and the Court having found that Duxbury had "direct and independent knowledge" of the information underlying these allegations as a result of his employment, it cannot be gainsaid that Relator obtained "direct and independent knowledge" of the "*essential facts*" of the "Kickback scheme" during his 1992-1998 employment.

IIB. The 1st Circuit Has Ruled Relator's Eight Representative Examples Of 'False Claims' Resulting From The Scheme Satisfied Rule 9(b) Pleading Requirements.

In its decision remanding this case, the 1st Circuit ruled that Relator's "*claim*" alleging a "Kickback scheme" met the heightened pleading requirements of Rule 9(b) regarding the submission of "*false claims*".¹⁰ In finding that Relator had pled with

¹⁰ *US ex rel. Duxbury v. Ortho Biotech Products LP*, 579 F 3d 13, 32 (1st Cir. 2009).

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particularity the submission of a representative number of “false claims” resulting from the alleged nationwide scheme, the 1st Circuit specifically referenced the allegations in paragraph 211 of the Amended Complaint regarding the submission of “*false claims*” by the eight “Duxbury Accounts”. The 1st Circuit found that Relator “set[] forth allegations of kickbacks provided by [Ortho] that resulted in the submission of *false claims* by eight healthcare providers in the Western United States” and that “as to each, Duxbury provides information as to the dates and amounts of the false claims filed by these providers with the Medicare program”.¹¹

The Court found, in particular, that Relator “alleged the submission of false claims across a large cross-section of providers that alleges the ‘who, what, where, and when’ of the allegedly false or fraudulent representation”.¹² The Court also found that “Duxbury has also alleged facts with respect to the medical providers he identifies that support his claim that [Ortho] intended to cause the submission of false claims”.¹³ In sum, the Court found that “Duxbury has alleged facts that false claims were in fact filed by the medical providers he identified, which further supports a strong inference that such claims were also filed nationwide”.¹⁴ The 1st Circuit concluded that “the factual evidence alleged here of the submission of false claims caused by [Ortho] at a cross-section of

¹¹ *US ex rel. Duxbury v. Ortho Biotech Products LP*, 579 F3d 13, 30 (1st Cir. 2009).

¹² *Id.* at 30.

¹³ *Id.* at 30.

¹⁴ *Id.* at 31.

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medical providers, is sufficient in this context” and therefore, “Duxbury’s allegations pass muster for purposes of Rule 9(b)”.¹⁵

III. REASONS WHY THE COURT SHOULD NOT ENTER THE “*ORDER*”

The Court should reject Ortho’s suggestion that an order be entered “strictly limiting” the Court’s “original source” jurisdiction geographically and temporally to just “Duxbury’s accounts” during the period of Relator’s employment. Ortho’s “Brief” at 9. It is based on both a fundamental misunderstanding of “original source” jurisdiction and a misapplication of the Supreme Court’s rulings in *Rockwell International Corp. v. United States*, 549 U.S. 457 (2007).

Ortho cites *Rockwell* repeatedly for the proposition that each “*claim*” in a Relator’s multi-*claim* complaint must pass “original source” muster. “Brief” at 2-4, 6. Ortho asserts that “given the original source rule and its limitation on ... jurisdiction” that “must be considered ... on a *claim-by-claim* basis”, and the fact that Relator “has no direct knowledge of [Ortho’s] activities occurring after he was terminated in 1998”, “relator cannot pursue any *claims* that postdate July 1998”. “Brief” at 4, 7. By doing so, Ortho completely ignores: we are dealing here not with multiple “*claims*” but with just the Relator’s “*claim*” regarding the “Kickback scheme” and the “*false claims*” resulting from it; the Supreme Court used “*claim*” to expressly refer to the “*allegations* regarding a fraudulent *scheme*” in a relator’s complaint not the “*false claims*” resulting from it; and that “original source” jurisdiction over the “*claim*” is dependent not on the the length of the Relator’s employment but on the Relator’s “direct and independent knowledge” of the “*essential facts*” of the “*scheme*”.

¹⁵ Id. at 32.

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By ignoring these fundamental realities, Ortho is, in effect requesting the Court to impose on an “original source” the additional requirement, not found in the statute, that the Relator have “direct knowledge” of all the activities of the “scheme” and each and every “*false claim*” under it. Such a dramatic and ill considered re-work of the statutory requirements would transform “knowledge” of the “essential facts” of the “scheme” based jurisdiction that should be applied “*claim*”-by-“*claim*” into “term of employment” based jurisdiction that is applied “*false claim*”-by-“*false claim*” – an outcome completely at odds with the statute, caselaw, and the rulings of this Court and the 1st Circuit in this case.

III.A. “Original Source” Jurisdiction Is Exercised On A “Knowledge” Of The “Essential Facts” Of The “*Scheme*” Basis.

“Original source” jurisdiction is exercised based on whether the relator has “direct and independent knowledge” of the “essential facts” of the “scheme”. The “public disclosure bar”, 31 USC 3730(e)(4)(A) and the “original source” exception, 31 USC 3730(e)(4)(B), do not use the words “*claim*” or “*false claim*”. The statutes speak of jurisdiction being exercised over the *allegations* of an *action*. 31 USC 3730(e)(4)(A) bars “jurisdiction over an *action* ... based upon the public disclosure of *allegations* or *transactions* ... unless ... the person bringing the *action* is an original source of the *information*”.¹⁶ The “original source” exception, 31 USC 3730(e)(4)(B), goes on to

¹⁶ 31 USC §3730(e)(4)(A) provides:

[The “Public Disclosure Bar”]

No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news

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define an “*original source*” as an “individual who has direct and independent *knowledge of the information* on which the *allegations* are based”.¹⁷

The statute expressly states that the court cannot exercise jurisdiction over the “*allegations*” unless the relator can demonstrate that they have “direct and independent knowledge of the information on which the *allegations* are based”. The Supreme Court made clear in *Rockwell*, the *allegations* of a *qui tam* complaint regarding a *fraudulent scheme* that the relator must have “direct and independent knowledge” of constitutes the “*claim*” in the relator’s complaint over which the court exercises “original source” jurisdiction.¹⁸ The statute does not speak of any further requirement concerning the exercise of the Court’s jurisdiction over a “*claim*” once the relator demonstrates they have “direct and independent knowledge” of the “*scheme*”.

As Ortho made crystal clear in its 1-17-07 Memorandum in support of its motion to dismiss, the “Public Disclosure Bar” and its “Original Source” exception, are triggered when there is a prior public disclosure of “*essentially the same*” allegations as the “*claim*”

media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

¹⁷ 31 USC §3730(e)(4)(B) provides:

[The “Original Source” Exception]

For purposes of this paragraph, “original source” means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

¹⁸ The court in *Rockwell* referred to the relator’s allegations that Rockwell was using defective machinery to make “insolid pondcrete” blocks as the “pondcrete *claim*” and made a point of noting that “new *allegations* regarding a fundamentally different *fraudulent scheme* require reevaluation of the Court’s *jurisdiction*” under 31 USC 3730(e)(4). *Rockwell* at 473, 476.

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in a relator's complaint.¹⁹ See also, *US ex rel. Boothe v. Sun Healthcare Group Inc.*, 496 F.3d 169, 1173-74 (10th Cir. 2007)(The court "reject[ed] the contention that a "time, place, and manner distinction is sufficient to escape the force of the public disclosure bar" in holding that relator's three claims concerning alleged fraudulent conduct that arose during later time periods was barred under 31 USC §3730(e)(4)(A) – "once the government knows the *essential facts* of a fraudulent *scheme*, it has enough information to discover *related frauds*")(emphasis added).

Ortho vociferously argued that because the "*essential facts*" of the Relator's "Kickback claim" were previously disclosed in the MCC therefore the "Public Disclosure Bar" was triggered and Relator had to demonstrate he qualified as an "original source" of the "*claim*" or face dismissal of the complaint.²⁰ Because the "*essential facts*" of the "Kickback scheme" alleged by Relator had been the subject of disclosure in the MCC, this Court had to determine - and did determine - that Relator came within the "original source" exception because, through his employment, Relator had obtained "direct and independent knowledge" of the "*essential facts*" of the "Kickback scheme". See **Section II A**. Under these circumstances, Ortho cannot seriously question that determinations of jurisdiction under the "Public Disclosure Bar" and its "original source" exception, turn on

¹⁹ 1-17-07 Ortho Memorandum p. 14 ("The general rule is that an FCA claim is 'based upon' a public disclosure if the 'allegations or transactions' noted in the disclosure are substantially or *essentially the same* as those alleged in the later claim"); See, Fn 12 containing numerous citations for this proposition; See, generally p. 5-20.

²⁰ Id. p. 5-6, 8 ("The *essential facts* supporting" Relator's "Kickback" claim "have long been publicly disclosed")(emphasis added).

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whether the “*essential facts*” of the “*scheme*” have been the subject of a previous public disclosure and the relator’s “direct and independent knowledge” of them.

It should also be noted that Ortho is improperly attempting to have it both ways. It successfully and correctly argued in its motion to dismiss that the “Public Disclosure Bar”, 31 USC 3730(e)(4)(A), should be read broadly to trigger the jurisdictional bar regarding a “*claim*” containing the “*same essential facts*” as the previous public disclosure.²¹ Ortho now urges the Court adopt the opposite position regarding the “original source” exception to the bar, 31 USC §3730(e)(4)(B) in order to substantially limit Relator’s recovery. This inconsistent and contradictory positioning deprives Ortho of the *bona fides* necessary to obtain the Court’s assistance.

IIIB. The Suggested Order Is Inconsistent With The Rulings In *Rockwell*

Ortho attempts to limit Relator’s ability to recover “*false claims*” that resulted from the “Kickback scheme” after Relator’s employment terminated because Relator did not have “direct knowledge” of those activities. This flies in the face of the Supreme Court’s rulings in *Rockwell*. Ortho completely misconstrues the rule annunciated by the Supreme Court in *Rockwell* that determination of “original source” jurisdiction has to be done on a “*claim-by-claim*” basis.²² Ortho cites to the rule as its cornerstone authority to

²¹ 1-17-07 Ortho Mem. p. 5, 6.

²² In *Rockwell* the court ruled that qualifying as an “original source to some *claim*” does not confer jurisdiction over other alleged *claims* to which the relator is not an original source:

Section 3730(e)(4) does not permit jurisdiction in gross just because a relator is an original source with respect to some claim. We, along with every court to have addressed the question, conclude that § 3730(e)(4) does not permit such claim smuggling. See United States ex rel. Merena v. SmithKline Beecham Corp., 205

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repeatedly admonish "[t]his Court therefore cannot allow relator to pursue any *kickback claims* based on any alleged [Ortho] conduct occurring after July 1998". "Brief" at 6 (emphasis added). Ortho's admonishment to the contrary, the Supreme Court's use of the term "*claim*" was an express reference to the "*claim*" in the relator's complaint alleging a fraudulent "*scheme*" and not to the "*false claims*" resulting from it.

The express application by the Supreme Court of the "*claim-by-claim*" rule to a relator's "*claim*" alleging a fraudulent *scheme* cannot be questioned. In announcing the rule, the Supreme Court specifically cited to Judge Alito's opinion in *United States ex rel. Merena v. SmithKline Beecham Corp.*, 205 F.3d 97, 102 (CA3 2000).²³ In *Merena*, Judge Alito ruled that "in applying section (e)(4), it seems clear that each *claim* in a multi-*claim* complaint must be treated as if it stood alone". *Id.* at 102. In doing so, Judge Alito expressly referred to each of the various "*schemes*" alleged in the relator's complaint as a "*claim*" over which the court had to determine it could exercise "original source" jurisdiction. *Merena, supra* at 98-99, 102 (relator's "complaint contained eight separate *claims*" including the "automated chemistry *scheme*" which the court also referred to as the "automated chemistry *claim*") (emphasis added).

Further evidence for the application of the *Rockwell* rule to a relator's "*claim*", and not the "*false claims*" sought to be recovered under it, is seen in the *Rockwell* court's

F.3d 97, 102 (CA3 2000) ... As then-Judge Alito explained, "[t]he plaintiff's decision to join all of his or her *claims* in a single lawsuit should not rescue *claims* that would have been doomed by *section (e)(4)* if they had been asserted in a separate action. And likewise, this joinder should not result in the dismissal of *claims* that would have otherwise survived." *SmithKline Beecham, supra*, at 102.

Rockwell at 476.

²³ *Id.* at 476.

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ultimate disposition of the relator's action. The issue before the court was whether the relator was entitled to share in the jury's "*false claim*" award for activities engaged in by Rockwell *after* relator's employment with Rockwell had ended, namely the submission of "*false claims*" for "poncrete blocks" that were "insolid". The fact that relator did not have "direct knowledge" of the post-employment "*false claims*" at issue was not the reason the court ruled that relator was not entitled to share in the recovery. The court ruled against the relator because the court found that relator did not have "direct and independent knowledge" of the "*claim*" i.e. the "allegations regarding the fraudulent scheme" that resulted in the "*false claims*" for "insolid pondcrete" being submitted. While the court found that Stone qualified as an "original source" for the "*claim*" in his complaint that Rockwell had an allegedly defectively designed system that Stone predicted would make "insolid pondcrete", that was not the "insolid pondcrete" "*claim*" on which the jury awarded damages. The jury found for the United States on the "*claim*" that the "pondcrete blocks" became "insolid" because Rockwell's foreman reduced the "cement-to-sludge ratio". Since the relator did not have "direct and independent knowledge" of this "*claim*" which came into existence "long after Stone had left" his employment, there was no basis on which to assert "original source" jurisdiction. *Rockwell* at 475-476.

Had the "cement-to-sludge ratio" "*scheme*" come into existence during Stone's tenure sufficient to provide Stone with "direct and independent knowledge" of the "*essential facts*" of the scheme, such as is the situation for Relator in this matter, there certainly would have been a basis, as there is here, on which to assert "original source" jurisdiction to the "*claim*" and relator's entitlement to recover the "false claims" under it.

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Under these circumstances, Ortho's repeated citation to *Rockwell* as purported support for denying Relator's right to pursue all of the "*false claims*" geographically and temporally resulting from the "Kickback scheme", is wholly inappropriate.

IIIC. The Suggested Order Is Directly Contrary To The Rulings Of This Court And The First Circuit In This Case.

Entering an order as suggested by Ortho would be directly contrary to the rulings of this Court regarding the application of the "Public Disclosure" and "First To File" bars that resulted in the exclusion of McClellan as a Relator. It would also be contrary to the rulings of the 1st Circuit concerning the application of Rule 9(b) to this complex fraud and the structure of the FCA and purpose of the "Public Disclosure Bar".

This Court in applying the "Public Disclosure Bar" opted for a "broader interpretation of 'based upon'" that triggered the application of the bar to McClellan's "claim" that incorporated "Kickback scheme" conduct that occurred at a later time period than Duxbury's but was not considered "*new*".²⁴ The Court believed this "broader interpretation" was "more consistent with the policies underlying the public disclosure bar".²⁵ The Court agreed with Ortho that "even if [McClellan] qualified" as an "original source" of the "Kickback claim" he would still be barred by the "First To File Bar" which "precludes a subsequent relator's claim that alleges the defendant engaged in the *same type of wrongdoing* as that claimed in a prior action even if the allegations cover a

²⁴ *US ex rel. Duxbury v. Ortho Biotech Products LP*, 551 F. Supp 2d 100, 109 (USDC DMA 2007).

²⁵ *Id.* at 108.

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different time period or location within a company”.²⁶ At Ortho’s urging the Court used Duxbury’s “*claim*” to bar McClellan because McClellan’s Kickback “*claim*”, though it incorporated the time period of the “*scheme*” after Duxbury’s employment terminated, was adjudged “essentially the same”. Now, Ortho urges the Court to take action again but this time to prevent Duxbury from recovering for that post-employment period because Ortho argues, the “*claim*” is *not* the same. The Court should not take up Ortho’s invitation to engage in such transparent gamesmanship.

Adoption of Ortho’s suggestion to “strictly limit” Relator from pursuing all the “*false claims*” resulting from the “*scheme*” would be inconsistent with the 1st Circuit’s relaxation of the particularity requirements of Rule 9(b) in complex cases like Medicare fraud. The court ruled that in complex fraud cases like this a “more flexible standard” is required and therefore a “relator could satisfy Rule 9(b) by providing factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim.”²⁷ Accordingly the 1st Circuit found sufficient that Relator “alleged the submission of false claims across a large cross-section of providers” “which further supports a strong inference that such claims were also filed nationwide”.²⁸ Adopting an artificial limit on “original source” jurisdiction that prevents

²⁶ Id.at 111.

²⁷ *US ex rel. Duxbury v. Ortho Biotech Products LP*, 579 F 3d 13, 29 (1st Cir. 2009).

²⁸ Id. at 30-31; Like the 1st Circuit, the other Circuits that have considered the issue have held that in “complex” cases alleging a “fraudulent scheme involve[ing] numerous transactions that occurred over a long period of time, the courts have found it impractical to require the plaintiff to plead the specifics with respect to each and every instance of fraudulent conduct”. *US ex rel Bledsoe v. Community Health Systems, Inc.*, 501 F.3d 493, 509-510 (11th Cir. 2007). “The examples that a relator provides will support more

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Relator from pursuing “false claims” on a geographic and temporal scale that is commensurate with the extent of the fraud would defeat the whole purpose of the court’s adopting a “more flexible standard”. See, *US ex rel Bledsoe v. Community Health Systems, Inc.*, 501 F.3d 493, 509 (11th Cir. 2007) (“were a court to consider the concept of a fraudulent scheme in an *excessively narrow fashion*, the policies promoted by the rule allowing a relator to plead examples, rather than every false claim, would be undermined”)(emphasis added).

In its “Brief” Ortho makes much of the intervention and prosecution rights of the Attorney General in *qui tam* suits to argue that Relator does not “need to stay in this case.” “Brief” at 5. Yet, the fact overlooked by Ortho but which looms large over this matter, is that Relator and Relator alone has been prosecuting this case on behalf of the taxpayers for more than seven years. The 1st Circuit in its exhaustive examination of the structure of the FCA and the history of the “Public Disclosure Bar” made a point of noting the problem of the “under-enforcement” of the FCA and the need to “encourage more private enforcements suits”.²⁹ The court pointed out that “[w]hile “public disclosure ... may h[ave] the benefit ... of providing public pressure on the government

generalized allegations of fraud ... to the extent that the relator's examples are *representative samples* of the broader class of claims”. Id. at 510 citing, *US ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 557 (8th Cir. 2006) (“Clearly, neither this court nor Rule 9(b) requires [a relator] to allege specific details of *every* alleged fraudulent claim forming the basis of [the relator's] complaint. However . . . [the relator] must provide *some* representative examples of [the defendants'] alleged fraudulent conduct, specifying the time, place, and content of their acts and the identity of the actors.”), *cert. denied* 127 S. Ct. 189, 166 L. Ed. 2d 142 (2006). See also, *US ex rel Clausen v. Laboratory Corporation of America, Inc.*, 290 F.3d 1301, 1314 (11th Cir. 2002)(where “fraud complex” plaintiff has to “allege at least some examples of actual false claims to lay a complete foundation for the rest of [the] allegations”).

²⁹ *US ex rel. Duxbury v. Ortho Biotech Products LP*, 579 F 3d 13, 27 (1st Cir. 2009).

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to act ... there also may arise situations when even that is not enough, and the government would benefit from suits brought by relators with substantial information of government fraud even though the outlines of the fraud are in the public domain.”³⁰ For that reason, the court “rejected readings of the ‘public disclosure’ bar that would create a new exclusion not articulated in the text which would discourage productive private enforcement”.³¹ Ortho’s suggested order that would impose additional requirements on the Relator “strictly limiting” Relators’s ability to pursue full recovery - requirements that are not “articulated in the text” – without question “would discourage productive private enforcement” by Relator that the 1st Circuit was keen to prevent. On that basis alone, Ortho’s suggested order should be rejected.

IV. CONCLUSION

For these reasons, Relator respectfully requests the Court reject Ortho’s suggested “*Order*” and allow the matter to proceed to discovery.

³⁰ Id. at 27.

³¹ Id. at 27.

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CERTIFICATE OF ELECTRONIC SERVICE

This is to certify that on the 18th day of January 2010 the above document was served on Ortho and the United States by electronic service.

/s/

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Attorney for Relator